- 1 A. I heard a figure but I don't want to
- 2 state it because it's not documented, so I would say I
- 3 don't know for sure.
- 4 Q. Well, if I told you it was over 75
- 5 hours, does that ring true to what you were told?
- 6 A. I heard it was about three days.
- 7 Q. Okay. That's pretty long, isn't it?
- 8 A. It is.
- 9 Q. Is it one of the longest you've ever
- 10 heard of?
- 11 A. No. There are -- autopsies are done a
- 12 week later.
- Okay. But certainly in a true
- 14 peripheral site like a femoral vein, you would expect
- there to be postmortem redistribution of digoxin at 70
- 16 hours; right?
- 17 A. I would.
- 18 Q. And would you expect there to be
- 19 postmortem redistribution of digoxin in an axillary
- 20 vein at 70 hours?
- 21 A. I think it would be in any site.
- 22 Q. Okay. Is digoxin lipophilic or
- 23 lipophobic?
- 24 A. It's more lipophilic, but it does have
- 25 water-soluble characteristics.

Page 69
Q. Are lipophilic compounds more likely to

- 2 undergo PMR than lipophobic?
- 3 A. Yes.
- 4 Q. Are you a member of the AAFS?
- 5 A. Yes. American Academy of Forensic
- 6 Sciences.

1

- 7 Q. Yes.
- 8 What is Dr. Middleberg's role at NMS
- 9 vis-a-vis your own?
- 10 A. Well, right now he is the vice president
- 11 of quality assurance. He still functions as a
- 12 forensic toxicologist.
- Before -- before Dr. Logan came on
- 14 board, he was in charge of the toxicological services
- 15 group.
- And then when Barry Logan joined us, Rob
- 17 moved into the QA department, though he still does a
- 18 lot of forensic tox, and Barry headed up the
- 19 toxicological services group.
- 20 Q. Okay. So I assume in this case you
- 21 don't know anything about when Mr. McCornack took his
- 22 last digoxin dose before death?
- 23 A. I do not.
- Q. Did you help draft the AutoText portions
- 25 that appear on Page 2 of Exhibit 8?

- 1 A. Some of these I was involved in in not
- 2 directly writing but certainly I had input into the
- 3 text itself.
- 4 Q. Okay. Do you have any --
- 5 A. The digoxin, I know I did not work with
- 6 the digoxin.
- But quinidine, atropine, ethyl alcohol,
- 8 and diltiazem are all part things that I did work over
- 9 the years.
- 10 Q. Is there any one source in the medical
- 11 literature that is the definitive statement on the
- 12 quantity by which digoxin will redistribute postmortem
- 13 at various times?
- 14 A. I don't know the answer to that. I
- 15 haven't seen any specific papers that I know of that
- 16 would answer that question.
- 17 Q. Are --
- 18 A. I'm sure there are studies in a limited
- 19 number of patients that, you know, we can glean
- 20 information from, but I don't know if it's definitive.
- Q. Okay. But you're aware that there's
- 22 literature that talks about quantity of
- 23 redistribution; right?
- A. Well, certainly.
- 25 Q. Or magnitude of redistribution?

- 1 A. Well, based on ratios between heart
- 2 blood, peripheral blood, yes.
- 3 Q. Is excess dose the only reason for
- 4 digoxin toxicity or an elevated serum level?
- 5 A. No.
- 6 Q. Would you expect there to be more
- 7 postmortem redistribution at 24 hours than 5 hours?
- 8 A. I would expect so.
- 9 O. More at 44 hours than 24 hours?
- 10 A. I expect so.
- 11 Q. And more at 75 than 44?
- 12 A. Unless -- unless we've gotten to a point
- 13 where, you know, things have stabilized and all the
- 14 concentrations in the body are the same.
- 15 Q. I assume in this case you're not going
- 16 to render any opinions to a reasonable probability as
- 17 to what the dose of Mr. McCornack's digoxin was in the
- 18 days leading to his death.
- 19 A. I will not.
- 20 Q. You're not going to render any opinions
- 21 to a probability about the -- what his serum digoxin
- level would have been had it been drawn prior to his
- 23 death.
- A. No, I would not.
- MR. ERNST: I'm going to object to that.

- 1 It's incomplete.
- 2 BY MR. MORIARTY:
- 3 0. Are you even going to render any
- opinions to a probability as to the likely range of
- 5 his serum level prior to death?
- 6 Α. Well, if I was given a hypothetical
- question based on his weight and normal body functions 7
- in terms of kidney function, et cetera, I could use 8
- 9 literature values to give you a ballpark estimate of
- 10 his antemortem level.
- 11 Would that require to use -- you to Q.
- 12 select some random magnitude of postmortem
- 13 redistribution?
- Well, if we're talking about antemortem, 14 Α.
- 15 there would not be any postmortem redistribution.
- 16 I'm sorry, maybe my question was bad. 0.
- 17 Would doing such a ballpark estimate
- 18 require you to assume a magnitude of the postmortem
- 19 redistribution?
- 20 Α. No. No. I'm not taking -- I'm not
- taking a level that we took postmortem and trying to 21
- 22 calculate back to antemortem.
- 23 What I'm saying is, to be clear, what I
- 24 would do is if you -- somebody were to give me the --
- 25 as much information as you could about the situation

PLAINTIFFS' EXHIBITS 012970

- 1 at the time, his body weight, his typical dose, his
- 2 kidney function being normal, et cetera, things like
- 3 that, and then based on the literature of volunteers
- 4 taking digoxin over a certain period of time, I would
- 5 say the typical range would be from X to Y.
- 6 O. Okay.
- 7 A. Okay?
- 8 Q. But extrapolating back from postmortem
- 9 to anti -- antemortem -- a-n-t-e -- mortem, is
- 10 typically not recommended; correct?
- 11 A. It's not recommended. It's fraught with
- 12 all kind of perils.
- 13 Q. And you've even said in other settings
- 14 that you can make estimates but they are not
- 15 necessarily accurate estimates; correct?
- 16 A. That's correct.
- 17 Q. And you can attempt correlations like
- 18 that, but you realize that the accuracy is not great;
- 19 correct?
- 20 A. Yes.
- 21 Q. And just so we're clear, this -- in
- 22 Exhibit 8 this diltiazem level of 630 nanograms per
- 23 milliliter, that is not a measurement of what Dan
- 24 McCornack's diltiazem level was just prior to his
- 25 death.

- 1 A. It is not.
- 2 Q. And the digoxin level of 3.6 is not a
- 3 measurement of what Dan's digoxin level was just prior
- 4 to his death.
- 5 A. I would be surprised if it was.
- 6 Q. More likely than not, both of those, had
- 7 they been measured prior to death, would be
- 8 substantially lower; correct?
- 9 MR. ERNST: Objection.
- 10 THE WITNESS: I don't know that for a
- 11 fact, but I'm assuming that's what would be the case.
- 12 BY MR. MORIARTY:
- 13 Q. More likely than not that's true?
- 14 A. More -- I'm sorry. More likely than
- 15 not, that's true.
- 16 Q. But you can't quantify that; correct?
- 17 A. Correct.
- 18 Q. Is there any peer-reviewed scientific
- 19 literature, to your knowledge, that gives a formula
- 20 for any reliable back calculating from postmortem
- 21 levels to antemortem levels of digoxin?
- 22 A. I don't know if it is a reliable
- 23 estimate, but what is normally done is you take some
- 24 of the pharmacokinetic parameters in antemortem
- 25 livers, such as volume distribution, and then measure

- 1 half life and dose and do a calculation starting with
- 2 the postmortem level, trying to get an antemortem
- 3 level or a dose that is given.
- 4 The problem there is that the -- the
- 5 volume of distribution has a range to it. The volumes
- of distribution have a significant range to it. And,
- 7 therefore, that's where the error comes in.
- Because you end up with very low levels
- 9 to very high levels, and that's why it's not very
- 10 accurate.
- 11 Q. Okay. And if I remember what you told
- 12 me before, you haven't published any article which
- 13 contains any sort of calculations or anything like
- 14 that on this subject.
- 15 A. That's correct.
- 16 Q. Have you ever told a coroner to base a
- 17 cause of death solely on a postmortem blood tox screen
- 18 for digoxin?
- MR. ERNST: Objection.
- THE WITNESS: Not that I'm aware of, no.
- 21 BY MR. MORIARTY:
- 22 Q. If you had, hypothetically, one sample,
- 23 so blood drawn from one site, and no other tissue
- 24 tested, and you knew that the specimen was drawn over
- 25 70 hours after death from an axillary vein, would you

Page 76 1 counsel a coroner to base a cause of death on a 2 postmortem blood result from that sort of draw? 3 MR. ERNST: Objection. THE WITNESS: With having one sample, I 5 would not. Unless -- unless the number was just so 6 outrageously large. 7 BY MR. MORIARTY: So, hypothetically, if Dr. Mason had 8 Q. 9 called you and said I'm looking at this diltiazem 10 result of 630 nanograms per milliliter, you know, it's 11 an axillary draw, non-ligated, over 70 hours after 12 death. 13 Dr. Barbieri, do you think that I should say that this man died of diltiazem toxicity? 14 15 What would you say? 16 Α. I would tell him probably not. 17 Q. Okay. 18 And I would say to him that the -- the Α. 19 blood serum ratio of diltiazem after -- you know, a study is around two and a half, and these levels are 20 21 typical -- or that level is typical of what we see in 22 postmortem cases and non-death cases related to 23 diltiazem. 24 And it's certainly nowhere near the 25 range in the literature of death cases caused by

Page 77 1 diltiazem. 2 0. Okay. 3 Α. So I would say that the diltiazem could be contributory to some degree based on the history, 5 but by itself, no way. 6 And you'd agree with me that a digoxin 7 level of 3.6 even in a living person who had given a serum sample is not necessarily fatal; correct? 8 9 Α. Correct. 10 Object. MR. ERNST: 11 BY MR. MORIARTY: 12 And so if Dr. Mason had called you and 0. 13 said, You know, Dr. Barbieri, I see your result of 3.6 14 nanograms per milliliter based on this specimen, would 15 you advise him to say that Dan McCornack died of 16 digoxin toxicity?

- 17 MR. ERNST: Objection.
- 18 THE WITNESS: I probably would not have
- 19 done that.
- 20 Can I add to that answer?
- 21 BY MR. MORIARTY:
- 22 Q. Sure.
- 23 A. I think it's important for everybody to
- 24 understand that people have died from digoxin at
- 25 levels that were well within therapeutic range as

Page 78 1 well. 2 So if he has no other pathology, you could say that certainly a level like that of digoxin 3 could be a cause of death because people die at 5 therapeutic levels as well. 6 Ο. Okav. 7 Α. Just based on that number, again, I would not definitively say that digoxin caused the 8 death. 9 10 MR. MORIARTY: How are we doing on time? 11 VIDEO OPERATOR: Good. Thirty-one 12 minutes left. 13 BY MR. MORIARTY: Do you still read the Journal of 14 Analytical Toxicology? 15 16 Α. Yes. 17 Are you still a reviewer for the Journal Q. 18 of Analytical Toxicology? 19 Α. Yes. 20 MR. MORIARTY: Why do I keep doing that? (Exhibit Barbieri-9 was marked for 21 22 identification.) BY MR. MORIARTY: 23 24 I'm handing you Dr. Barbieri Exhibit 9. 0. 25 This is a letter to the editor in the

Page 79 1 Journal of Analytical Toxicology in the July/August 2 issue of this year; correct? Yes. 3 Α. Q. 2011; right? Α. Yes. 6 0. Do you know Fred Apple? 7 Α. Yes, I do. Is he a reliable coroner? 8 Q. 9 I'm going to object. MR. ERNST: 10 11 BY MR. MORIARTY: 12 To your knowledge. 0. 13 MR. ERNST: Object. MR. MORIARTY: Okay. I'll withdraw the 14 15 question. 16 BY MR. MORIARTY: 17 What is Fred Apple's reputation in the Q. 18 scientific community, if you know? 19 Well, he has a -- he has a following, 20 and he has done some very good work over the years. 21 There are things that he has written that I completely 22 disagree with as well. 23 0. Okay. 24 But he certainly has a decent reputation Α. 25 as a -- as a medical toxicologist.

- 1 Q. Now, when the editors of the Journal put
- 2 a letter to the editor in, do any of the reviewers,
- 3 like you, get to look it over before it's published?
- 4 A. No, generally not. This is usually
- 5 handled by the editorial staff.
- 6 Q. All right. Have you read this before
- 7 today?
- 8 A. No. No. This is a -- this is a recent
- 9 one. I have not read this -- I have not seen this one
- 10 yet. I haven't opened up that July/August issue.
- 11 Q. Behind an issue or two, are you?
- 12 A. I am.
- 13 Q. Okay. Let me just ask you about a
- 14 couple passages in this.
- 15 Right here in -- partway through the
- 16 second paragraph it says, The scientific fact is that
- 17 PMR occurs in both central (heart) blood as well as in
- 18 peripheral (femoral) blood, as shown for numerous
- 19 drugs in Table I.
- 20 Did I read that correctly?
- 21 A. Yes, you did.
- 22 Q. Do you agree with that?
- 23 A. Yes --
- MR. ERNST: I'm going to --
- 25 THE WITNESS: I'm sorry.

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Page 81
 1
                  MR. ERNST: -- object to this line of
 2
     questioning.
 3
     BY MR. MORIARTY:
          Q.
                   Is digoxin in Table I?
                  MR. ERNST: Can I have a continuing
 6
     objection?
 7
                  MR. MORIARTY:
                                 Yes.
 8
                  MR. ERNST:
                               Thank you.
     BY MR. MORIARTY:
 9
10
                   Is digoxin in Table I?
          0.
11
          Α.
                  Yes, digoxin is listed in Table I.
12
                   For both heart and peripheral?
          0.
13
          Α.
                  That's what it says.
                   On the second page, at the end of this
14
          0.
15
     paragraph that continues on from the preceding page,
16
     it says, When heart or peripheral blood is drawn --
17
     are you with me?
18
          Α.
                   I have it.
19
          0.
                   -- it more likely than not does not
20
     reflect the blood concentration at the time of death,
21
     but reflects the combination of tissue-bound drug that
22
     has been released into the blood/fluid that is drawn
23
     at autopsy hours after death.
24
                   Did I read it correctly?
25
          Α.
                   Yes.
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Page 82 1 Do you agree with that? Ο. 2 MR. ERNST: Objection. That is a -- that is a 3 THE WITNESS: general statement for many drugs, not specific to 5 digoxin. And so, yes, I do agree with that. 6 BY MR. MORIARTY: 7 Q. And it goes on to say, I opine that this needs to be carefully considered in cause of death 8 9 determinations when interpretation of PM drug 10 concentrations is backed by literature in support of 11 PMR. 12 Did I read it correctly? 13 Α. Yes. And do you agree with it? 14 0. 15 MR. ERNST: Objection. 16 THE WITNESS: I think it's a fair statement, so I would agree with it. 17 18 BY MR. MORIARTY: 19 It goes on to say, This is especially 20 true in death cases in which blood concentrations may 21 be overinterpreted as the cause of death based on the 22 assumption that the peripheral PM blood concentration 23 is an accurate record of the perimortem blood 24 concentration at the time of death. 25 Did I read it correctly?

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Page 83 1 Α. Yes. 2 0. Do you agree with that? 3 MR. ERNST: Objection. THE WITNESS: Yes, I do. 5 BY MR. MORIARTY: 6 Do you know anything about whether 0. 7 Dr. Mason and his staff have the ability and skill to draw vitreous samples? 8 9 I don't know for sure, but I'm assuming 10 that they do. 11 (Exhibit Barbieri-10 was marked for 12 identification.) 13 BY MR. MORIARTY: I have marked this International Journal 14 of Legal Medicine, year 2000, I think it's Exhibit 10, 15 isn't it? 16 17 Yes. Α. 18 Have you ever read this before? Ο. 19 Α. This article, no, I have not. 20 Well, basically what they're trying to Q. 21 do is figure out if -- because postmortem blood is 22 unreliable, they're questioning whether vitreous is 23 any better. 24 Is that a gross description of what this 25 is about?

Page 84 1 Α. It looks that way. 2 Okay. And it says here, Postmortem MDMA 0. 3 concentrations in vitreous humor were closer to the antemortem blood levels when compared to cardiac blood 5 samples. 6 Do you see that? 7 Α. Yes, I see that. And MDMA is basically methamphetamine; 8 Q. right? 9 Well, it's a derivative of 10 Α. 11 methamphetamine. 12 0. Okay. 13 Α. It's Ecstasy, the other name. So in the second column in the first 14 0. paragraph do you see where they're footnoting 5? 15 16 Α. Yes. Under -- after femoral vein? 17 18 Yes. Ο. 19 Α. It says 5. 20 Q. After --21 MR. MORIARTY: Do you see where I am, 22 Don? 23 MR. ERNST: No. 24 MR. MORIARTY: Above where your pen is. 25 MR. ERNST: Thank you.

Page 85 1 BY MR. MORIARTY: 2 However, bearing in mind this general 0. 3 recommendation, a single blood sample is often insufficient to draw appropriate conclusions. Another sample, tissue or fluid, should 6 not only be used as an analytical control for the 7 blood level determined but could also provide information on the pharmacokinetic phase and as a 8 9 result the time of drug intake. 10 Do you agree with that? 11 MR. ERNST: Objection. 12 THE WITNESS: I don't know. I'd have to 13 read through to understand what they're saying here --BY MR. MORIARTY: 14 15 All right. 0. 16 Α. -- without taking a snapshot of it. 17 Well, the bottom line is that even your Q.

- 18 company advocates more than one type of sample for
- 19 cross-checking purposes.
- 20 Α. Well, that I -- that I agree with, yes.
- 21 Q. Okay.
- 22 (Exhibit Barbieri-11 was marked for
- identification.) 23
- BY MR. MORIARTY: 24
- 25 I'm handing you Dr. Barbieri Number 11. Q.

Page 86 1 MR. MORIARTY: Sorry, Don. 2 BY MR. MORIARTY: 3 Have you ever seen this article before? 0. Α. Yes, I have. Is it in your own archive of materials 6 about this subject? 7 Α. Yes, it is. So let's go to Page 237. It says 8 Q. 9 Examples of drugs known to undergo PMR. 10 Do you see that section? 11 Α. Yes. 12 Digoxin is the second one listed; 0. 13 correct? Yes. Uh-huh. 14 Α. And if you go to Page 238, the second 15 0. 16 column -- I'm sorry. Oh, I'm sorry. It got buried 17 there. 18 VIDEO OPERATOR: Yeah, it's making a 19 noise. 20 BY MR. MORIARTY: 21 Q. Okay. Let's go back. 22 I'm at Page 238 on the bottom of the 23 left column where it says Practical implications for 24 the medical toxicologist? 25 Α. Uh-huh.

Page 87 1 MR. ERNST: Uh-huh. 2 BY MR. MORIARTY: 3 0. It says, Peripheral blood is less likely to be subject to the postmortem elevations in drug 5 concentrations seen in central blood sources such as 6 the heart. 7 Do you agree with that? Α. Yes. 9 Further down in that same paragraph, 0. 10 Heart blood is probably one of the least informative 11 areas for sampling because the redistribution of drug 12 from the lung, liver, or myocardium affects the 13 resulting drug concentration and, therefore, should 14 not be used without a corresponding peripheral blood 15 sample. 16 Do you see that? 17 I do. Α. 18 Ο. Do you agree? 19 Α. Yeah, let me just clarify. 20 They're talking about concentrations found in heart blood. And that I certainly agree 21 22 with. 23 0. Okay. 24 Α. Heart blood can be very informative in

terms of screening a compound.

25

- 1 Q. Okay. In the next section, it's
- 2 Alternative to blood, and they're talking about other
- 3 tissues. It says, Of these, the vitreous, because of
- 4 its isolation, appears to be less susceptible than
- 5 blood to postmortem changes.
- It is also a more simple environment
- 7 than putrefied blood containing 98 to 99 percent
- 8 water.
- 9 Do you agree with that?
- 10 A. Yes, I do.
- 11 (Exhibit Barbieri-12 was marked for
- 12 identification.)
- 13 BY MR. MORIARTY:
- 14 Q. Dr. Barbieri, I asked this Keith Gibson
- 15 a number of questions about medical literature.
- 16 Did Mr. Ernst forward to you any of the
- 17 medical literature that I asked Keith Gibson about?
- 18 A. No, he did not.
- 19 Q. Have you seen this Ferner article from
- 20 the British Journal of Clinical Pharmacology?
- 21 A. I don't remember this one.
- Q. Okay. Well, I only want to ask you
- about one paragraph.
- MR. ERNST: I'm going to object. He
- 25 hasn't read it.

Page 89 1 MR. MORIARTY: Okay. Your objection is 2 duly noted. 3 BY MR. MORIARTY: Q. Go to the last page. I mean the last 5 page of the article, not the bibliography. 6 Α. With a figure on the top? 7 Q. Yes, sir. Α. Okay. 9 And when I ask you this question, I'm 0. 10 asking -- I want to ask you specifically in regard to 11 a postmortem axillary vein, non-ligated specimen drawn 12 70 hours after death regarding digoxin. Okay? 13 Α. Okay. 14 0. Keep that in mind as I ask about it. 15 Α. Okay. 16 It says, There is no reliable or obvious 0. 17 connection between concentrations measured in life and 18 subsequent to death. 19 Consequently, concentrations measured 20 after death cannot generally be interpreted to yield 21 concentrations present before death. 22 Objection. MR. ERNST:

23 BY MR. MORIARTY:

Q. Did I read that correctly?

25 A. You did.

Page 90 All right. Would you agree with me that 1 that is true regarding the type of specimen that I 2 just described? 3 MR. ERNST: Objection. 5 THE WITNESS: I would have to agree with 6 you. (Exhibit Barbieri-13 was marked for 7 identification.) 8 BY MR. MORIARTY: 9 10 I believe this is Number 13. 0. 11 This is Clarke's lab manual, isn't it? 12 Α. Uh-huh. Yes. 13 Q. Part of it. 14 Α. Yes. 15 Q. Volume 1. 16 You've seen this before. 17 Well, I know the -- I know the volume. Α. 18 You use this? 0. 19 Α. Yes. 20 Q. So let's go to Page 96. 21 And, again, I was asking you earlier 22 about whether various -- that's Page 96; right? 23 Α. 96. 24 Okay. I was asking you earlier about 0. 25 whether other matrices are good for cross-checking

Page 91 your results as opposed to one sample. And I want to 1 2 ask you about this vitreous paragraph. Okay? 3 Α. Okay. Q. About halfway through that section it 5 says, Vitreous humor has also been used increasingly 6 for the measurement of drugs. 7 Do you agree with that? Α. Yes. 8 9 For example, digoxin concentrations 0. 10 increase markedly in postmortem cardiac blood but do 11 not increase significantly in vitreous humor. 12 Do you see that statement? 13 Α. Yes. Did I read it correctly? 14 0. 15 Α. You did. 16 Does it come from that Vorpahl and Coe 0. 17 article, to the best of your knowledge? 18 Α. Yes, it does. 19 MR. ERNST: Objection. Objection. 20 THE WITNESS: I'm sorry. MR. ERNST: Unless there's a foundation. 21 22 THE WITNESS: Yes, it does, and I know 23 that article.

You've read it.

24

25

BY MR. MORIARTY:

Q.

Page 92 1 Α. Yes. 2 0. Do you agree with the statement? Yes. 3 Α. Q. Therefore, vitreous digoxin 5 concentrations give a better indication of perimortem concentrations than does heart blood. 6 7 Do you agree? Α. There's a weight of evidence that 8 9 suggests that that is true. 10 All right. And when you say --0. 11 Α. Whether I -- whether I specifically 12 agree, I'm still on the fence there. But I know that 13 the weight of evidence is that vitreous digoxin does give a better indication of the concentrations. 14 15 And when you say "the weight of 0. 16 evidence," you're talking about the scientific evidence. 17 18 Α. Yes, I am. 19 Q. Let's go to Page 105, second column. 20 In the middle of the paragraph under Blood and/or tissue distribution. 21 22 Are you in the general area? 23 Α. Yes, I have it. 24 It says, While concentrations of some 0. 25 drugs can increase by as much as two to tenfold after

- 1 death in postmortem blood, concentrations in tissues
- 2 such as liver remain relatively stable.
- 3 Do you agree with that?
- 4 A. Well, the first part of the sentence I
- 5 do agree with. I mean, tricyclic antidepressants, for
- 6 example, can go up to 15 times.
- 7 Concentrations in liver being relatively
- 8 stable, I don't know the answer to that, whether I
- 9 agree or not.
- 10 Q. All right.
- 11 A. I think it largely depends upon where
- 12 the section of the liver is taken from --
- 13 Q. Okay.
- 14 A. -- which can definitely lead to
- 15 concentrations.
- 16 Q. Have you read articles about digoxin in
- 17 which they talk about that drug undergoing PMR by two
- 18 to tenfold after death?
- 19 A. No.
- 20 Q. At Page 106 in the second column, the
- 21 last sentence in that carryover paragraph --
- A. Here (indicating), okay.
- 23 Q. Right there.
- It says, In most instances,
- 25 pharmacokinetic calculations using postmortem blood

Page 94 measurements are rarely defensible forensically. 1 2 Do you agree with that? 3 MR. ERNST: Objection. THE WITNESS: Well, this is -- this is 5 pretty clear to say that you can't really defend it. You can defend with the calculations that one makes 6 7 and with all the caveats associated with them, as I tried to explain before. 8 9 So I would say that I'm not going to, 10 you know, say that this is not true because I think 11 you can defend what you've done, but the calculations 12 are suspect. 13 BY MR. MORIARTY: 14 Are you telling me that you can defend 15 what you've done, but the results aren't necessarily 16 accurate? 17 That's true. Α. 18 MR. ERNST: Objection. 19 THE WITNESS: Yes. 20 (Exhibit Barbieri-14 was marked for identification.) 21 22 BY MR. MORIARTY: 23 Let's look at Exhibit 14, which 0. Okav. is Volume -- from Volume 2 of Clarke's. 24 25 This is the monograph on digoxin, is it

Page 95 1 not? 2 Α. Yes. 3 0. And if you go to Page 918, under Disposition in the body, it says, Digoxin is rapidly 5 distributed throughout the body and less than 20 6 percent of the total digoxin in the body is located in 7 the blood. 8 Do you see that? 9 Α. Yes. 10 Do you agree? Q. 11 Α. Yes. 12 Is that similar to what Baselt is saying 0. 13 in his book? 14 Α. Yes. 15 And then it says, High concentrations 0. are found in the heart, brain, and kidneys, but the 16 17 skeletal muscles form the largest digoxin store. 18 Did I read that correctly? 19 Α. Yes. 20 Q. Do you agree? 21 Again, we talked about this, and that's Α. 22 true not on a concentration basis but on a total body 23 load. 24 All right. And is it consistent with 25 Baselt's text?

Page 96 1 Α. Yes. 2 0. Now, under Therapeutic Concentration it 3 says, In serum usually in the range of 1 to 2.5. Now, that's micrograms per liter; 5 correct? 6 Α. Yes. 7 Q. Okay. (Exhibit Barbieri-15 was marked for 8 identification.) 9 10 BY MR. MORIARTY: 11 Here is Exhibit 15, the Cook and Q. Braithwaite article from the Journal of Clinical 12 13 Pathology. 14 Have you ever seen this before? 15 Α. Yes, I have. 16 Is it in your archive of scientific 0. 17 materials regarding digoxin? I don't know if I saved this one. This 18 Α. 19 goes back, you know, many years. 20 Q. But you've read it. 21 Α. But I have read it. 22 Okay. All I want to ask you about is Ο. 23 the last paragraph of the article. It begins by 24 saying, Our study shows that a high degree of error 25 can arise from attempting to predict antemortem

Page 97 1 concentrations from postmortem concentrations --2 MR. ERNST: I'm going to object. MR. MORIARTY: What's the matter? 3 It's the last paragraph of the 5 article --6 MR. ERNST: I object. It's -- you're 7 talking about a whole range of drugs. I object. MR. MORIARTY: Okay. I just -- I didn't 8 9 know if you were in the right place. 10 Let me start over --11 MR. ERNST: Yeah, I'm in the right 12 place. I just -- it's an improper cross-exam. I 13 object. BY MR. MORIARTY: 14 15 Okay. Let me ask you about this last 0. 16 paragraph. 17 It says, Our study shows that a high 18 degree of error can arise from attempting to predict 19 antemortem concentrations from postmortem 20 concentrations and emphasizes the need for continued 21 research into this area of pathology practice. 22 In the absence of such data, estimates 23 of circulating drug concentrations during life should 24 not be made. 25 First, did I read it correctly?

Page 98 1 Α. You did. 2 0. Second, so far as digoxin is concerned, 3 do you agree with that? MR. ERNST: Objection. 5 THE WITNESS: Well, certainly the 6 beginning in terms of the high degree of error can 7 arise, and I've stated that before today. So I certainly agree there. 8 9 And they're saying definitely the 10 circulating concentrations should not be made. 11 may be some utility in calculating a concentration, 12 especially if their levels are significantly greater 13 than what one would expect. 14 So I don't know if I agree with that 15 second sentence because I think there may be some 16 utility at least getting ballpark numbers to look at 17 -- and what -- what we have. 18 Again, realizing all the caveats that 19 I've talked about. 20 BY MR. MORIARTY: 21 Q. Sure. 22 You wouldn't do it as a forensic 23 toxicologist based on a 3.6 postmortem Dig level drawn 24 under these circumstances, would you?

Α.

No --

25

```
Page 99
 1
                  MR. ERNST:
                               I'm just -- objection.
 2
                  What was the -- I didn't -- it was an
 3
     incomplete question.
                  MR. MORIARTY: Can you read my question
 5
     back.
 6
                   (The court reporter read back the
 7
     following:
 8
                   "O.
                        Sure.
                   "You wouldn't do it as a forensic
 9
10
     toxicologist based on a 3.6 postmortem Dig level drawn
11
     under these circumstances, would you?")
12
                  MR. MORIARTY: And what was his answer?
13
                   (The court reporter read back the
     following:
14
15
                   "A.
                       No --")
16
                  THE WITNESS: No, I didn't answer.
17
                  COURT REPORTER: I'm sorry.
                                                 There was
18
     an objection, and he was interrupted by the objection.
19
     BY MR. MORIARTY:
20
          0.
                  Did you answer my question?
21
          Α.
                  No, I started but I didn't answer.
22
                  COURT REPORTER: Right.
23
     BY MR. MORIARTY:
24
                  Answer my question.
          0.
25
          Α.
                  Okay.
```

Page 100 1 MR. ERNST: My objection stands. 2 THE WITNESS: Okay. As I said before, I would not do it with digoxin in this case. 3 MR. MORIARTY: Okay. (Exhibit Barbieri-16 was marked for 6 identification.) 7 BY MR. MORIARTY: I'm handing you Dr. Barbieri Number 16. 8 Q. 9 I'm going to try to get this question in before the 10 break. 11 Go to Page 541. 12 Have you seen this article, by the way? 13 Α. Yes, I have. Read it? 14 0. 15 Α. Read it. Saved it. 16 Under Practical Consequences in Forensic 0. 17 Toxicology, it says, From practical -- From a 18 practical point of view, the respect of some 19 precautionary measures can limit misinterpretations. 20 Do you agree with that? 21 Α. Yes. 22 It is very important in postmortem 0. 23 testing to be able to compare concentrations in 24 several blood and tissue samples even if reference 25 values for drug concentrations in tissues are often

PLAINTIFFS' EXHIBITS 012998

Page 101 1 missing. 2 MR. ERNST: Objection. 3 BY MR. MORIARTY: Do you agree? Q. Α. I do. 6 0. Okay. That's all I want to ask you 7 about this. We have to take a five-minute break. 8 9 When we come back, I will be able to wrap this up 10 within 15 minutes or so. 11 VIDEO OPERATOR: Going off the record at 12 12:50. 13 (A recess was taken from 12:50 to 14 12:59 p.m.) 15 VIDEO OPERATOR: We're back on the 16 record at 12:59. 17 You may proceed. 18 BY MR. MORIARTY: 19 Dr. Barbieri, do you use Flanagan's 20 toxicology book in your practice at all? 21 Α. No, I don't. 22 I'm just trying to get through these 0. 23 articles and see if I need to ask you about them. 24 Are you familiar with Graham Jones? 25 Α. Yes.

Page 102 1 What's his reputation in the 2 toxicological community? Excellent. 3 Α. Q. Have you read any of his books or 5 articles? 6 Α. Yes, I've read several -- several of his 7 articles. (Exhibit Barbieri-17 was marked for 8 identification.) 9 10 BY MR. MORIARTY: 11 Well, let me ask you about Barbieri Q. 12 Exhibit 17, which is a chapter from a book called the 13 Postmortem Toxicology of Abused Drugs by Karch. 14 Do you have that book? 15 Α. It's on -- it's on -- it's not my book, 16 but it's on our shelves, yes. 17 Do you ever refer to it? Q. 18 Α. Once in a while. 19 Q. Is it considered pretty reliable? 20 Α. There's good things and bad things about 21 it. 22 All right. Let me ask you about Graham Q. 23 Jones' chapter in particular called the Interpretation 24 of Postmortem Drug Levels. All right?

Α.

Uh-huh.

25

Page 103 1 MR. ERNST: I will object. There's no 2 foundation. 3 BY MR. MORIARTY: Q. All right. So let's go to Page 115. Do you see that section called Postmortem Specimens? 6 7 Α. Yes. It says, Relying on a toxicology result 8 0. 9 from a single specimen can be misleading because of 10 the postmortem changes that can occur. 11 Do you agree with that? 12 Α. Yes. 13 MR. ERNST: Objection. BY MR. MORIARTY: 14 15 The last sentence in that section, it 0. says, It is good forensic practice to have multiple 16 17 specimens available or at least blood specimens from 18 different sites in the body because of the potential 19 difficulties in interpreting postmortem toxicology 20 results. 21 Do you agree with that? 22 MR. ERNST: I will object. 23 THE WITNESS: Yes, I do. 24 BY MR. MORIARTY: 25 So on the next page, at the end of that Q.

- 1 -- at the end of the section before Vitreous, it says,
- 2 Since blood concentrations of some drugs have the
- 3 potential for marked postmortem change, it is good
- 4 practice to analyze blood obtained from more than one
- 5 site, plus tissue or other specimens where this may be
- 6 useful.
- 7 MR. ERNST: Objection.
- 8 BY MR. MORIARTY:
- 9 O. Do you agree?
- 10 A. Yes. In general, yes.
- 11 Q. And in the section on Vitreous, which is
- one of these alternative specimens that they're
- 13 talking about, the second sentence says, However,
- 14 vitreous humor has also been useful for a number of
- 15 drugs.
- 16 For example, it is well known that
- 17 digoxin concentrations will rise after death in
- 18 cardiac blood, due to postmortem redistribution from
- 19 myocardial tissue, and possibly other organs.
- 20 Consequently, vitreous digoxin
- 21 concentrations are more likely to reflect those in
- 22 antemortem plasma.
- Did I read it correctly?
- A. You did.
- 25 Q. Do you agree?

Page 105 1 I do. And that -- that references again to Vorpahl and Coe. 2 Okay. So if we go back to Page 123, 3 0. there is a section called Estimation of Amount 5 Ingested from Blood Levels. 6 Do you see that? 7 Α. I have it. MR. ERNST: I'm going to object. 8 Objection. 9 10 BY MR. MORIARTY: 11 Q. The first sentence --12 MR. ERNST: Can I have a continuing 13 objection to this entire article? 14 MR. MORIARTY: Yes. 15 MR. ERNST: Thank you. BY MR. MORIARTY: 16 17 Given the foregoing discussion, it Q. 18 should go without saying that using pharmacokinetic 19 calculations to try to estimate dosage given a 20 postmortem blood concentration is of virtually no 21 value and can be extremely misleading. 22 Do you agree? 23 Α. No. 24 Q. Okay. 25 Α. I don't.

- 1 Q. Why?
- A. Well, it can be misleading, and, as I
- 3 stated before, I think there may be some benefit to
- 4 knowing ballpark numbers and ballpark estimates. So
- 5 to say it's no value I think is very strong.
- 6 Q. Yeah, but here they're talking about
- 7 dose ingested, not the antemortem level.
- 8 A. Well, I know that. But you can do the
- 9 calculation -- you can reverse the calculations and
- 10 get the dose back.
- 11 Again, the -- based on the caveats it
- 12 talked about before, there can be a wide range between
- 13 those.
- 14 Q. Okay.
- 15 A. And though, in some respects, at least
- in his respect, he says it's of no value, I think
- there is some value to at least get a ballpark
- 18 estimate of where you are.
- 19 Q. All right. But you wouldn't do it in
- 20 this case.
- 21 A. In this particular case --
- MR. ERNST: Objection.
- THE WITNESS: I'm sorry.
- In this particular case I think we're
- 25 dealing with a drug that should not be estimated

Page 107 1 levels. 2 MR. MORIARTY: All right. Okay. (Exhibit Barbieri-18 was marked for 3 identification.) 5 BY MR. MORIARTY: 6 0. Okay. Let's ask you about Dr. Barbieri 7 Number 18. Have you read any of Gideon Koren's work 8 on postmortem redistribution of digoxin? 9 10 Α. No, I haven't. 11 Q. Are you sure? 12 I'm pretty sure. Α. 13 Q. Okay. I know Dr. Koren's work from his work on 14 Α. alcohol and cocaine, but I don't remember reading 15 16 anything on digoxin. 17 All right. What is his general Q. 18 reputation in the scientific community? 19 Α. It's very good. 20 0. So as you can see from the abstract, 21 they actually had some patients in whom they had --22 did some studies; correct? 23 Α. Yes. It states here 47 children. 24 Okay. So let's go to the left column of 0. 25 the first page of this, which is Page 1210.

Page 108 1 It says, However, excessive serum 2 concentrations of the cardiac glycoside should not 3 automatically be interpreted as reflecting toxicity. Do you agree? Α. I do. 6 Ο. Let's go back to Page 1212. 7 MR. ERNST: Just a minute. There's no foundation for this. 8 9 Continued objection. 10 Is that agreed, Counsel? 11 MR. MORIARTY: Yes, you can have a 12 continuing objection. 13 MR. ERNST: Thank you. BY MR. MORTARTY: 14 15 Let's go to the last sentence on the 0. 16 page. 17 An attempt to prove digoxin intoxication as a cause of death may be hampered by the fact that 18 19 postmortem levels may be 1.5 to ten times higher than 20 antemortem levels. 21 Do you see that? 22 Α. I do. 23 0. Do you agree? 24 Well, I certainly agree that trying to Α. 25 produce -- to prove digoxin intoxication as a cause of

- 1 death may be hampered.
- 2 Q. Okay.
- 3 A. That postmortem levels are this range, I
- 4 don't have any basis for that, so I can't agree to the
- 5 numbers.
- 6 Q. Are you --
- 7 A. But in terms of the general statement,
- 8 yes, I agree.
- 9 Q. Are you saying you have no basis because
- 10 you haven't done the experiments?
- 11 A. I don't have enough data to make a
- determination that it's going to be 1.5 to ten times
- 13 higher than antemortem.
- Q. Okay. And have you read enough
- 15 literature to know whether this is contained in the
- 16 greater body of literature on this subject?
- 17 A. To go up to ten times higher? I don't
- 18 believe so.
- 19 Q. All right.
- 20 A. In the lower range I would say we're
- 21 probably closer to it.
- 22 Q. Okay.
- MR. MORIARTY: Okay, everybody, we have
- 24 to take a time-out.
- VIDEO OPERATOR: Let's go off the record

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Page 110
 1
     at 1:09.
 2
                   (A recess was taken from 1:09 to
 3
     1:11 p.m.)
                   VIDEO OPERATOR: We're back on the
 5
     record at 1:11.
 6
                   You may proceed.
 7
                   MR. MORIARTY: Thank you.
                   (Exhibit Barbieri-19 was marked for
 8
     identification.)
 9
10
     BY MR. MORIARTY:
11
          Q.
                   Okay. Let me ask you about Dr. Barbieri
12
     Number 19.
13
                   Do you know who Derrick Pounder is?
14
          Α.
                   Yes.
15
          Q.
                   What is his reputation in the scientific
16
     community?
17
                   It's very good.
          Α.
18
                   And this is from I think Cyril Wecht's
          0.
19
     pathology text.
20
                         Legal Medicine, 1993, Cyril Wecht,
21
     M.D., J.D.
                He's a coroner from Pittsburgh --
22
          Α.
                   I know him.
23
                   -- for many years.
          Q.
                   I know Dr. Wecht.
24
          Α.
25
          Q.
                   Is he still practicing?
```

Page 111 1 Α. Yes. 2 0. Amazing. 3 Have you ever seen this book? Α. No, I haven't. 5 MR. ERNST: May I have a continuing 6 objection? 7 MR. MORIARTY: Yes, you can. BY MR. MORIARTY: 8 9 Have you ever used it? 0. 10 Α. No. 11 Let me ask you just a few questions from Q. 12 it. 13 In the beginning they're talking about the purpose of postmortem analysis for drugs; is that 14 right? 15 16 Α. Yes. 17 And then a couple sentences down it Q. 18 says, In all of this there is an underlying 19 presumption that drug concentrations in blood and 20 other biological fluids and tissues remain constant in 21 a corpse, whatever the delay between death and the 22 collection of samples. 23 In recent years it has become 24 increasingly clear that for most drugs, this 25 presumption is false.

Page 112 1 Do you agree with that? 2 I do. Α. Turn, please, to Page 175. 3 Q. It's -- Page 175, it's the second full 5 paragraph. 6 Α. Okav. 7 Q. And it talks about diltiazem and digoxin. 8 9 Do you see that? 10 Α. Yes. 11 Can you just read that paragraph to Q. 12 It starts with Drug concentrations in 13 cardiac blood, and ends with is the likely mechanism. (Witness reviews document.) Okay, I've 14 Α. read it. 15 16 Do you agree with it? 0. 17 Well, again, I have to -- I have to take Α. 18 him at his word that -- the last thing about 30 times 19 that of blood. But it wouldn't be unusual coming from 20 cardiac blood -- I'm sorry -- coming from myocardium, 21 the cardiac blood to be that high. 22 Q. Okay. 23 So in general, yes, I do agree with the 24 paragraph. 25 Q. Got it.

- 1 And then if you go to the next page,
- 2 176, the first full paragraph begins with One approach
- 3 to the problem of postmortem drug changes in blood has
- 4 been to look for alternative or corroborating tissues
- 5 for analysis.
- You agree with that, don't you?
- 7 A. Yes.
- 8 Q. And, lastly, please go to Page 187.
- 9 The last paragraph, In conclusion.
- 10 A. Okay.
- 11 Q. Do you see that?
- 12 A. Uh-huh.
- 13 Q. The second sentence says, For
- interpretive purposes, the ideal toxicological sample
- is a peripheral blood specimen obtained from a ligated
- 16 vessel immediately after death.
- Do you agree with that so far?
- 18 A. Yes.
- 19 Q. Then it goes on to say, All autopsy
- 20 samples fall short of this ideal, but the more they do
- 21 so, the more contentious will be the interpretation of
- 22 the analytical results.
- Do you agree with that?
- 24 A. I do.
- MR. MORIARTY: Do you want to break and

Page 114 1 talk or just go? 2 MS. DONAHUE: Just go. 3 MR. MORIARTY: Okay. I am going to pass the witness. 5 Did I give you a copy of this? 6 MS. DONAHUE: No. 7 Thank you. I think I need your microphone. 8 9 VIDEO OPERATOR: Yes. 10 MS. DONAHUE: Thank you. 11 EXAMINATION 12 BY MS. DONAHUE: 13 I quess it's afternoon now, so good afternoon, Dr. Barbieri. 14 15 Α. Good afternoon. 16 I just have a few short follow-up 0. 17 questions for you. 18 I introduced myself off the record, but 19 my name is Alicia Donahue and I represent the Mylan 20 defendants in this case. 21 Okay, Alicia, thank you. Α. 22 Q. Thanks. 23 Let's see. You talked a little bit 24 about the various conversations you had with Mr. Ernst 25 and his partner on the case.

- 1 How much time in total have you spent
- 2 working on this case, preparing for deposition?
- 3 A. Not a lot at all. I spent about an hour
- 4 -- other than the phone calls, which in total was
- 5 about an hour or so.
- 6 O. Uh-huh.
- 7 A. I spent about an hour yesterday going
- 8 through the litigation package. I had reviewed it
- 9 very briefly after our first conversation when I
- 10 obtained the records, just to get a feel for the
- 11 case. So that's about it.
- 12 Q. Okay. And what is your -- what are you
- 13 charging Mr. Ernst per hour for doing that work?
- 14 A. I believe it's 400 an hour. But I don't
- 15 -- I don't handle that, so I'm just guessing on that.
- 16 Q. So as you sit here today, do you have
- 17 any idea in your mind about how much has been billed
- 18 for your time spent on this case to date?
- 19 A. Nothing has been billed so far.
- 20 Q. Do you have an estimate as to how much
- 21 that bill would be based on the time you've spent to
- 22 date?
- 23 A. It's probably going to be somewhere
- 24 around four hours' worth of time. Assuming we're here
- for a couple hours now, so we're already three-plus

Page 116 1 hours into it. 2 Ο. Okay. 3 Α. It depends how long it goes obviously. MR. ERNST: That includes this 5 deposition? 6 THE WITNESS: It includes that, yeah. BY MS. DONAHUE: 7 All right. In regard to what has been 8 0. 9 marked as Exhibit 4, which is the expert disclosure in 10 this case, and that you were asked questions about 11 that earlier, you mentioned -- and I'm just 12 paraphrasing -- but you mentioned talking to Mr. Ernst 13 and telling him that you objected to one of the statements in Exhibit 4? 14 15 Α. Well, I -- it wasn't just one --16 0. I hand that to you. 17 -- it wasn't just one of the Α. 18 It was the -- the whole tenure of the statements. 19 statement of what I would testify to. And that's my question. Can you tell --20 0. 21 can you elaborate for me what exactly your objections 22 were to Exhibit 4? 23 And first let's start by telling --24 telling me, when did you tell Mr. Ernst you had

objections to Exhibit 4?

25

- 1 A. It was a couple weeks after the first
- 2 conversation that we had.
- 3 Q. And can you give me a time frame of when
- 4 that occurred?
- 5 A. I probably have a specific date.
- 6 Q. If you refer to the phone log --
- 7 A. I don't have the --
- 8 Q. -- would that be helpful?
- 9 I'll give you back the exhibits. I
- 10 think the phone log is in there.
- 11 A. No, it would not be in here. Let's see.
- 12 (Witness reviews documents.) Well, this
- isn't -- this isn't specific as to when we spoke. But
- 14 it was certainly in the range of June the 8th to the
- 15 16th, somewhere in that area.
- 16 Q. Thanks.
- 17 All right. So then getting --
- 18 A. And my objection was that -- well, how
- 19 this came about -- again, as I think I tried to
- 20 explain before -- I was very confused after our first
- 21 initial conversations about why I was being deposed
- 22 because I knew that this package had been done before
- 23 by Matt McMullin.
- 24 And so I -- we contacted Mr. Moriarty's
- 25 office to get a clarification of did he really want me

- 1 to testify on this case because I didn't know if I
- 2 could really add to what was presented previously.
- 3 And then he sent me back a deposition --
- 4 the beginning of the deposition notice with just Pages
- 5 9 and 10 of this document.
- And I read through this and basically I
- 7 took it as the Ernst law firm made a decision that I
- 8 would be talking about causation and all these things
- 9 and distribution and toxicity and et cetera.
- 10 And I -- I had no knowledge of this
- 11 specific case, as I tried to explain. And so I got
- 12 quite upset because this is not normally what I see.
- 13 Usually people will contact me ahead of
- 14 time and say, Here's what we want to talk about.
- 15 Here's what I'm going to write out. I'm going to send
- 16 you a copy of this and we'll go over it.
- 17 This was brand new to me. And so I
- 18 basically hit the ceiling.
- 19 Q. And?
- 20 A. And so I contacted his office and let
- 21 him know that I was very unhappy about what
- 22 happened -- what transpired.
- 23 He then -- through missing some phone
- 24 calls back and forth, we eventually hooked up and he
- 25 was very, very cordial and very apologetic and tried

- 1 to explain to me what this was about and that this was
- 2 their best attempt prior to contacting me as to what I
- 3 may be testifying to.
- 4 And so I took him at his word and I
- 5 accepted his apology and I said, We're just going to
- 6 move forward on that.
- 7 Q. You talked about what you're used to and
- 8 what normally happens in situations like this, and
- 9 that would be that you would have been contacted prior
- 10 to the disclosure being served.
- 11 A. Yes.
- 12 Q. That's been your experience in the
- 13 past.
- 14 A. Yes.
- 15 Q. And that did not occur in this case.
- A. No, it did not.
- 17 O. And you never discussed with Mr. Ernst
- 18 or anyone in his office prior to May 15th -- or May
- 19 16th of 2011 any of the opinions that are reflected in
- 20 the disclosure as those that you would provide in this
- 21 case.
- 22 A. That's correct. I had no -- no contact
- 23 with his office at all.
- 24 Q. And the fact of the matter is, I believe
- 25 your testimony today is that you do not intend to

- 1 render any opinions, any expert opinions, in regard to
- 2 this case, other than the methodology that your lab
- 3 uses and the findings of your lab in regard to the
- 4 blood tests performed on the sample.
- 5 MR. ERNST: Objection. He already has.
- 6 THE WITNESS: Well, I've rendered some
- 7 opinions based upon digoxin in general. And I tried
- 8 not to be specific with the case, but obviously the
- 9 question was focused on the level.
- 10 And so I didn't want to. And -- but
- 11 circumstances, I tried to answer honestly.
- 12 BY MS. DONAHUE:
- 13 Q. You do not intend to render any opinions
- in this case in regard to the cause of Mr. McCornack's
- 15 death; is that correct?
- 16 A. No, I do not.
- 17 Q. Nor any opinions in regard to the
- 18 liability of any of the defendants for that death.
- 19 A. That's correct, I will not.
- Q. When you had your conversation with
- 21 Mr. Ernst where you said you were pretty upset after
- 22 reviewing the disclosure that's been marked as Exhibit
- 23 4, did he tell you why he didn't contact you prior to
- 24 serving the disclosure and discuss your testimony with
- 25 you?

- 1 A. I don't know the exact words he used,
- 2 but the -- what I got out of it was they were moving
- 3 forward with this case, they wanted me eventually to
- 4 testify, and whether it was an oversight on their
- 5 part -- I don't know the specifics of it -- but they
- 6 did their best in terms of putting down what they
- 7 thought I would testify to.
- 8 That's what I got out of it.
- 9 O. Did any -- is there any reflection in
- 10 your records, Doctor, that anyone from Mr. Ernst's
- 11 office attempted to contact you and discuss the
- 12 opinions and testimony that's referenced in Exhibit 4
- as testimony that you will provide, prior to serving
- 14 it on May 16th, 2011?
- 15 A. No.
- MS. DONAHUE: That's all the questions I
- 17 have. Thank you very much.
- 18 EXAMINATION
- 19 BY MR. ERNST:
- 20 Q. Good morning, Doctor.
- A. Good morning.
- Q. We should clarify a number of things
- 23 here.
- Doctor, looking at what has been
- 25 previously marked as Exhibit Number 8, would you look

Page 122 1 at that document for me, please. 2 Α. Yes. 3 0. And what is it, please? Α. This is the second report that I 5 generated based on the blood testing for Daniel 6 McCornack to the Santa Cruz County coroner. 7 Q. And did you sign that document? Α. I did. 9 Are you the person that is mentioned as 0. 10 the individual that supervised the test for the 11 digoxin on the blood sample taken from Mr. McCornack 12 after his death? 13 Α. No. I did not supervise the testing for digoxin. 14 Did you sign Exhibit 8? 15 0. 16 Α. I did. 17 And your purpose in signing it was what? Q. 18 My purpose in signing it is that I Α. 19 reviewed all the data.

- 20 0. I see. I'm sorry.
- I reviewed all the data. As I said 21 Α.
- 22 before, some of it original, some of it not.
- 23 The digoxin level I did not review the
- 24 original data, but it was on the computer, and I
- 25 published the results based upon what the laboratory

- 1 staff did and the review of that data.
- 2 Q. How long have you worked for NMS?
- 3 A. Almost 13 years.
- 4 Q. Now, is your name on this -- is yours
- 5 the only name on this report as the -- having signed
- 6 the report with the digoxin level of 3.6?
- 7 A. That's correct.
- 8 Q. Circling back, looking at your CV, which
- 9 has been marked as Exhibit 1, I want to just take you
- 10 through a couple of things.
- 11 A. Okay. Certainly.
- 12 Q. Doctor, do you have a Ph.D.?
- 13 A. I do.
- 14 O. In what?
- 15 A. Pharmacology.
- 16 Q. And you received that from where?
- 17 A. The Philadelphia College of Pharmacy and
- 18 Science.
- 19 Q. And when was that?
- 20 A. 1976.
- 21 Q. And you did your undergraduate study
- 22 where?
- 23 A. My undergraduate was at the same
- 24 college. I have three degrees from the same
- 25 institution.

- 1 Q. And those three degrees are?
- 2 A. Bachelor of Science in pharmacy, 1970; a
- 3 Master's in Science in pharmacology in 1972; and my
- 4 Ph.D. in 1976.
- 5 Q. And you have testified as an expert in
- 6 toxicology many times, both in criminal cases and in
- 7 civil cases?
- 8 A. Yes.
- 9 Q. And Exhibit 8 was generated by NMS, your
- 10 employer, and you in this case; true?
- 11 A. Yes.
- 12 Q. Does it accurately reflect the testing
- 13 that was done by NMS?
- 14 A. Yes, it does.
- 15 Q. And was the testing by NMS done in a
- 16 scientifically appropriate fashion?
- 17 A. Yes, it was.
- 18 Q. And you can testify as the person who
- 19 signed the report that, in fact, that testing was done
- 20 in an appropriate scientific fashion?
- 21 A. Yes. Yes, I do.
- 22 Q. And does Exhibit 8 accurately reflect
- 23 the findings of that -- of those tests?
- A. Yes, it does.
- 25 Q. Now, looking back at the report, Doctor,

Page 125 you're aware that Mr. McCornack died on March 23rd, 1 2 2008? Yes. 3 Α. Q. And that --That's not from the report. That's from Α. 6 other documents in the folder. 7 Q. In the file. And when you were first contacted by me, it was relayed to you that you were a non-retained 9 10 expert; true? 11 Α. Yes. 12 And, in fact, I told you that I just 0. 13 wanted to have you testify about what you know, what 14 you knew, what you thought about the testing procedure 15 that was done and any ramifications about that; true? 16 MS. DONAHUE: Objection. 17 MR. MORIARTY: Objection. Leading. And I'll take a continuing objection to leading your own 18 19 expert --20 MS. DONAHUE: Join. 21 MR. MORIARTY: -- if you don't mind. 22 MS. DONAHUE: Join. Join. 23 MR. ERNST: Actually, I might want to 24 use this deposition testimony, so I would appreciate 25 if you would ask -- or just make the objection so that

- 1 if there is a problem, I will be able to cure it.
- 2 Okay?
- 3 MR. MORIARTY: Sure.
- 4 BY MR. ERNST:
- 5 O. Doctor, did we discuss that I wanted to
- 6 have you testify with having not reviewed any
- 7 particular documents of this case, just about what you
- 8 know or have observed and understood about the testing
- 9 procedures by NMS?
- 10 A. You did.
- 11 Q. And there was some confusion about when
- 12 you were designated as an expert.
- But apparently you contacted
- 14 Mr. Moriarty's office and asked about why you were
- 15 being deposed?
- 16 A. Yes.
- 17 Q. And did you speak with Mr. Moriarty at
- 18 the time?
- 19 A. No, I spoke with no one.
- 20 Q. All right. And thereafter you were sent
- 21 a disclosure.
- 22 A. Yes.
- 23 Q. And after the disclosure was sent, you
- 24 and I had a conversation where, if there was
- 25 miscommunication, we both sort of apologized and said,

- 1 look, I just want to know what's in your mind as a
- 2 toxicologist when these tests were performed.
- 3 A. Yes, that --
- 4 MS. DONAHUE: Objection. Leading.
- 5 THE WITNESS: -- that is fair and
- 6 accurate.
- 7 BY MR. ERNST:
- 8 Q. Did I ask you -- did I indicate to you
- 9 that during your deposition we would just be asking
- 10 you what you know and understood about the testing
- 11 procedures and any ramifications that you might have
- 12 from that?
- 13 A. I think you phrased it as some
- 14 hypotheticals that may come up. But, yes, we did.
- Okay. Now, one of the things that I
- 16 want to ask you about, and I have a hypothetical, but
- 17 before I get there, I want to ask about the testing of
- 18 digoxin.
- 19 NMS regularly tests for digoxin if they
- 20 are asked to do so.
- 21 A. Well, we will test for digoxin if we're
- 22 asked to do so. It's not necessarily on a regular
- 23 basis. We don't have a regular digoxin test we run
- 24 every day. But we will test for digoxin as requested.
- 25 Q. And in this particular case, what client

- 1 requested that you test for the digoxin?
- 2 A. It came from the office of the Santa
- 3 Cruz County coroner.
- 4 Q. Now, just in reviewing the document, do
- 5 you know why the request to review digoxin came at
- 6 this particular date?
- 7 A. No, other than from the phone log notes,
- 8 there was a conversation from a Sergeant Burt, I
- 9 believe, who actually made the request.
- 10 Q. I want you to -- I want to talk about
- 11 the 3.6 number.
- Taken by itself with a digoxin level of
- 13 3.6 postmortem, does that mean anything to you as a
- 14 toxicologist?
- 15 A. Well, 3.6 in the broad scope of things
- 16 for a postmortem blood sample is not exceedingly high.
- 17 If this were an antemortem serum or
- 18 plasma sample or even a whole blood sample that was
- 19 taken antemortem, this would -- as I explained to you,
- 20 this would be higher than the typical therapeutic
- 21 concentration that one may see.
- 22 Q. It would give you concern as a
- 23 toxicologist.
- A. Well, it would certainly, you know,
- 25 raise a flag, again, depending on what the sample was,

- 1 when it was taken, how it was taken, et cetera. But
- 2 it's nothing to turn around and say, Ignore it.
- 3 Q. Right.
- 4 You would want to do something with it
- 5 as a toxicologist.
- 6 MR. MORIARTY: Objection.
- 7 MS. DONAHUE: Objection.
- 8 THE WITNESS: No, that I can't state I
- 9 won't do something with it. We did something with
- 10 it. We published the number.
- 11 BY MR. ERNST:
- 12 Q. Now, I want to ask you -- I'm going to
- ask you a hypothetical question, and I have some
- 14 things that I want you to assume. And there's going
- 15 to be a list of them, so I want to make it clear.
- 16 A. Okay.
- 17 Q. I want you to assume that this blood
- 18 sample was taken from Dan McCornack who was 45 years
- 19 old at the time of his death.
- I want you to assume that his kidney
- 21 function was normal.
- I want you to assume that he weighed
- 23 approximately 220 pounds.
- I want you to assume that he was taking
- a 0.25 Digitek tablet twice per day, once in the

- 1 morning and once in the evening with his evening meal,
- 2 and at breakfast.
- I want you to assume that he was
- 4 regularly tested for digoxin levels by his treating
- 5 physician, that he had been taking digoxin for
- 6 approximately 15 to 20 years, and in the previous year
- 7 he'd been tested and his digoxin level was 1.6.
- I want you to assume that he was
- 9 tested -- and the 1.6 was from May 15th of '07 and his
- 10 blood was 1.6 nanograms per milliliter.
- I want you to assume that he was taking
- 12 his medication in an appropriate and compliant
- 13 fashion.
- I want you to assume that a family
- 15 member saw him take his medication, digoxin, the
- evening of March 22nd, 2008, at approximately 6:00 to
- 17 8:00 p.m.
- I want you to assume that his digoxin
- 19 medication was in a pill dispenser for which he had
- 20 his pills segregated to take.
- I want you to assume that he was with
- 22 four other families on a Easter trip camping in Big
- 23 Sur in a motor home.
- I want you to assume that he had been
- 25 compliant in his medication, taking his medication,

- 1 and the doctor, his treating doctor, had so testified.
- I want you to assume that his wife was
- 3 awakened by him at 12:30 a.m. on March 23rd, 2008, by
- 4 his snorting and inability to breathe.
- I want you to assume that his wife began
- 6 CPR, called 911, and that the rescue personnel arrived
- 7 and he was pronounced dead at 12:52 a.m. on March
- 8 23rd, 2008.
- I want you to assume that an autopsy was
- 10 done on March 26th, 2008, at 7:30 a.m.
- 11 And I want you to assume that blood was
- 12 drawn from a peripheral limb, that means an axillary
- 13 vein of the arm.
- And I want you to assume that the
- 15 coroner that took the blood cut the axillary vein and
- 16 pressed the blood out from the wrist of the arm down
- into the pooled area where he -- it was picked up.
- I want you to assume that at the time of
- 19 his autopsy, the doctor opined that the death was
- 20 cardiac arrest due to ventricular arrhythmia due to
- 21 atrial fibrillation due to hypertensive
- 22 arthrosclerotic cardiovascular disease.
- And I want you to assume that
- 24 thereafter, on or about May 2nd, 2008, a -- there was
- 25 a recall of the drug that Mr. McCornack was taking --

- 1 taken, in Digitek, and that recall was dated early May
- 2 2008, some five weeks after he died.
- 3 And thereafter, and only thereafter, did
- 4 Dr. Mason, the coroner, request digoxin test on the
- 5 blood of Mr. McCornack.
- 6 That blood was in the custody and
- 7 control of NMS, and that test that was performed on
- 8 the digoxin was the test that you have in front of
- 9 you, Exhibit 8.
- 10 Thereafter, the coroner reviewed the
- 11 medical records of Mr. McCornack from his treating
- 12 physician as well as his cardiologist and only after
- 13 review of all that material the coroner changed the
- 14 death certificate listing the cause of death to be
- 15 cardiac arrest due to ventricular arrhythmia due to
- 16 digoxin toxicity due to digoxin poisoning.
- 17 If all of these facts that I have given
- 18 you are accurate, would the blood level of 3.6 be
- 19 consistent with digoxin toxicity, digoxin poisoning
- 20 that could lead to cardiac arrest due to ventricular
- 21 arrhythmia?
- MS. DONAHUE: Objection.
- MR. MORIARTY: Objection. Form and
- 24 otherwise.
- Go ahead.

Page 133 1 Possibly. Though I can't THE WITNESS: 2 state that with any kind of scientific certainty. BY MR. ERNST: 3 Q. Right. I am asking you as a forensic 6 toxicologist to go back to Exhibit 5. 7 And on Exhibit 5, which you indicated you were familiar with, which is the AHFS Drug 8 9 Information, there's a statement that reads, on Page 10 1729, Serum concentrations of digoxin should be 11 interpreted in the overall clinical context. 12 All right. That's what it says. 13 the language that is also present is, In adults, toxicity is usually, but not always, associated with 14 15 steady-state plasma digoxin concentrations greater 16 than 2.0 nanograms per milliliter. 17 Is that true? 18 Α. Yes, what page are you on, just to --19 Q. 1729. 20 A better question is, Doctor, it's true 21 that steady-state plasma concentrations greater than 22 2.0 nanograms per milliliter are generally considered 23 toxic; true? 24 MR. MORIARTY: Objection. 25 THE WITNESS: Well, again, not

- 1 necessarily. I mean, this statement is true as it's
- 2 written.
- 3 Again, it says toxicity is usually, but
- 4 not always, associated with Dig concentrations greater
- 5 than 2.0 nanograms per mL. That is a true statement.
- 6 Okay?
- 7 Now, again, there are -- there are
- 8 individuals who have levels of -- these are --
- 9 antemortem therapeutic levels of digoxin above 2.0
- 10 nanograms per mL that are surviving as we sit here
- 11 today.
- 12 There are also individuals who have
- 13 levels below 2.0 nanograms per mL of digoxin in their
- 14 serum that have died from digoxin.
- 15 So the therapeutic index of digoxin,
- 16 which means the ratio between the toxicity and the --
- 17 the therapeutic level of digoxin, is very low.
- 18 And it is a dangerous drug. And in an
- 19 individual who has cardiac problems, it can be a
- 20 lifesaving drug and at the same time it can be a drug
- 21 that can cause problems.
- 22 So in answer to the hypothetical that
- 23 you gave me, I'll restate that, yes, it is certainly
- 24 possible that digoxin was involved in his death.
- 25 And it's also likely or it's possible

- 1 that digoxin had no role in his death, that his
- 2 pathology caused that.
- 3 BY MR. ERNST:
- 4 Q. Just -- but you don't have an opinion on
- 5 that. You just have -- I'm asking about the 3.6
- 6 level.
- 7 A. I understand that.
- 8 Q. So the 3.6 level is what you've termed a
- 9 starting point.
- 10 A. Yes.
- 11 Q. Now, I want to go back and talk about
- 12 the test for a moment. And this is Exhibit 8.
- 13 A. Yes, it is.
- 14 Q. And everything in Exhibit 8 is true and
- 15 accurate according to what you are testifying here
- 16 today and what you know; true?
- 17 A. Yes, it is.
- 18 MR. ERNST: Counsel, I would move
- 19 Exhibit 8 into evidence.
- 20 Do you have any objection?
- MR. MORIARTY: Yes.
- MS. DONAHUE: Yes.
- MR. ERNST: And would you state your
- 24 objection for the record.
- VIDEO OPERATOR: Could you put the mic